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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,545	11/28/2003	John H. Crowe	010023-000710US	3279

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EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,545	CROWE ET AL.	
	Examiner	Art Unit	
	Sheridan R. MacAuley	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22 and 48-61, drawn to a method for loading a preservative into a biological sample, classified in class 435, subclass 2.

Note that election of this group will also require the election of species of preservative solutions and gradients. See species election requirement below.

II. Claims 24-32, drawn to biological compositions, classified in class 435, subclass 2.

Note that election of this group will also require the election of species of biological compositions. See species election requirement below.

III. Claims 34-38, drawn to a process for processing biological samples, classified in class 435, subclass 2.

IV. Claims 39-41, drawn to a process for preserving protein structure in a biological sample, classified in class 435, subclass 2.

V. Claims 42-47, drawn to a dehydrated composition, classified in class 435, subclass 2.

Note that election of this group will also require the election of species of agonists. See species election requirement below.

The inventions are distinct, each from the other because of the following reasons:

5. Inventions of Groups I, II and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product claimed in Group II can be made by a materially different process, and the process claimed in Group I can be used to make a materially different product. For example, the product claimed in Group II could be made by recombinantly expressing a protein in a biological specimen that would raise its glass transition temperature prior to preserving the specimen with a preservative solution. Also, the process claimed in Group I could be used to make a biological sample which was not dehydrated, and need not be used to make a dehydrated sample, as claimed in Group V.

6. Inventions of Groups II, III, IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products claimed in Groups II and V can be made by materially different processes than those claimed in Groups III and IV. For example, the composition of Group V could be made by a process where the biological samples are suspended in the preservative solution at a concentration of less than about 10^8 biological samples per milliliter prior to freeze-

drying, or where the sample is not stored and rehydrated. Also, the product claimed in Group II can be made by a process that does not require dehydration or freeze-drying.

7. Inventions of Groups III and IV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different modes of operation. For example, the method of Group III requires freeze-drying and recovering a percentage of the freeze-dried samples, whereas the method of Group IV requires dehydration of the biological sample, storage, and subsequent rehydration. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

8. Inventions of Groups III and IV and Group I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combinations claimed in Groups III and IV require providing a preservative solution having a preservative, water and protein, whereas the subcombination of Group I has the additional feature that it has a higher glass transition temperature than for a solution

having no protein. The subcombination has separate utility such as in a process where the preserved samples are not dehydrated.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

9. Inventions of Groups II and V are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed do not overlap in scope. The composition of Group I comprises a preservative, water and a protein that increases the glass transition temperature of the biological sample, whereas the composition of Group V comprises freeze-dried biological samples that are rehydratable. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

10. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Species Election Requirement

11. Some of the Groups set forth above of the instant application contain claims directed to the following patentably distinct groups of species:

A. If applicant elects Group I, election is also required of the various species of preservative solutions recited in claims 2-6. For example, applicant may elect a preservative solution comprising a gradient of glass transition temperature to a water content ranging from about 50 to about 900 at a water content of less than about 0.40 grams of water per gram of dry weight of preservative and protein (recited in claim 2), a preservative solution wherein the glass transition temperature increases at a water content of less than about 0.4 grams of water per gram dry weight of preservative and protein (recited in claim 3), or a preservative solution comprising a greater rate of glass transition temperature per water content increase at a water content of less than about 0.15 grams of water per gram dry weight of preservative and protein than at a water content of greater than about 0.15 grams of water per gram dry weight of preservative and protein (recited in claim 5).

B. If applicant elects Group I, election is also required of the various species of gradients recited in claims 13-19. For example, applicant may elect a gradient of the

glass transition temperature to the water content ranging from about 50 to about 150 at a water content ranging from about 0.20 to about 0.30 grams of water per gram of dry weight of preservative or protein (recited in claim 16), or a gradient of the glass transition temperature to the water content ranging from about 700 to about 900 at a water content ranging from about 00.15 to about 0.20 grams of water per gram of dry weight of preservative or protein (recited in claim 18).

C. If applicant elects Group II, election is also required of the various species of biological compositions recited in claims 26-30. For example, applicant may elect a composition wherein a gradient of the glass transition temperature to the water content ranges from about 50 to about 150 at a water content ranging from about 0.20 to about 0.30 grams of water per gram of dry weight of biological sample (recited in claim 27), or a composition wherein a gradient of the glass transition temperature to the water content ranges from about 700 to about 900 at a water content ranging from about 0.15 to about 0.2 grams of water per gram of dry weight of biological sample (recited in claim 29).

D. If applicant elects Group V, election is required of the species of agonists. Applicant may elect thrombin (recited in claim 43) or ristocetin (recited in claims 44-47).

12. The species are independent or distinct for the following reasons:

13. Inventions of species groups A, B, C and D are directed to related related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are

mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different effect. For example, the various qualities of the compositions and gradients recited in species groups A, B and C would result in a materially different product. Also, the agonists claimed in species group D are a protease (thrombin) and an antibiotic (ristocetin), having materially different physical and chemical properties. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic for species groups A and B, claim 25 is generic for species group C, and claim 42 is generic for species of group D.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Notice of Potential Rejoinder

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is

(571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on (571) 272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

ZACHARIAH LUCAS
PATENT EXAMINER